

## REMARKS

### Status of the Claims

#### *Pending claims*

Claims 1 to 92 are currently pending.

#### *Claims canceled and added in the instant amendment*

In the present response, claims 1 to 41 and 56 to 92 are canceled, without prejudice, and claims 93 to 102 are added. Accordingly, after the entry of the instant amendment, claims 42 to 55 and 93 to 102 will be pending and under examination.

#### *Restriction Requirement and Election*

In the restriction requirement October 2, 2003, the Patent Office alleged that the pending claims of the application were directed to nine separate and distinct inventions under 35 U.S.C. §121.

In Applicants' response to the Restriction Requirement, Group IV, claims 42 to 55, drawn to methods of generating a variant, was elected.

#### *Outstanding Rejections*

Claims 42 to 55 are rejected under 35 USC §112, second paragraph. Claims 42, 43 and 50 are rejected under 35 USC §102(b) as allegedly anticipated by Trakulnaleamsai, et al., (1995) Ann. N.Y. Acad. Sci. 750:158-165 (hereinafter "Trakulnaleamsai"), as evidenced by Loprasert et al. (1989) J. Bacter. 171(9):4871-4875 (hereinafter "Loprasert"). Claims 42 to 55 are rejected under 35 USC §103(a) as allegedly unpatentable over Trakulnaleamsai in view of Short, U.S. Patent No. 5,939,250 (hereinafter "the Short '250 patent"). Claims 42, 43, 54 and 55 are rejected under 35 USC §103(a) as allegedly unpatentable over Trakulnaleamsai in view of Short, U.S. Patent No. 6,479,258 (hereinafter "the Short '258 patent"). Applicants respectfully traverse all outstanding objections to the specification and rejections of the claims.

### Support for Claim Amendments

The specification sets forth an extensive description of the invention in the new and amended claims. Support for claims directed to sequences of the invention having at least Support for claims directed to sequences of the invention having at least 50%, 55%, 60%, 65%,

70%, 75%, 80%, 85%, 90%, 95%, 96%, 97%, 98% or 99% nucleotide or amino acid residue identity can be found, inter alia, on page 9, lines 21 to 29, and page 56, lines 1 to 5, of the specification. Applicants submit that no new matter is introduced by the present amendments.

Information Disclosure Statement

Applicants thank the Examiner for noting an Information Disclosure Statement has not yet been filed. An Information Disclosure Statement and Form PTO 1449 is being submitted under a separate cover.

Issues under 35 U.S.C. §112, second paragraph

The Patent Office has rejected claims 42 to 55 for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard and the invention.

It is alleged that the terms “sequence complementary thereto” and “fragments comprising ... thereof” in claim 42 are indefinite. The instant amendment addresses this issue.

Issues under 35 U.S.C. §102

*Trakulnaleamsai and Loprasert*

Claims 42, 43 and 50 are rejected under 35 USC §102(b) as allegedly anticipated by Trakulnaleamsai, as evidenced by Loprasert.

The legal standard for anticipation under 35 U.S.C. §102 is one of strict identity. To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention.

The Patent Office alleges that Trakulnaleamsai teaches random mutagenesis of a *Bacillus stearothermophilus* catalase gene. However, Trakulnaleamsai does not teach a nucleic acid of the invention or a method using a nucleic acid, e.g., a sequence as set forth in SEQ ID NO:7 or a sequence having at least about 50% sequence identity to a sequence as set forth in SEQ ID NO:7, or, (after entry of the instant amendment) a sequence as set forth in SEQ ID NO:5 or a sequence having at least about 65% sequence identity to a sequence as set forth in SEQ ID NO:5. Accordingly, Trakulnaleamsai is not a single prior source that contains each and every limitation of the claimed invention.

The Patent Office alleges that Loprasert teaches a catalase gene 64% identical to SEQ ID NO:5. After entry of the instant amendment, the claimed methods of the invention use, inter alia, a sequence having at least about 65% sequence identity to a sequence as set forth in SEQ ID NO:5. Accordingly, Loprasert does not teach a nucleic acid of the invention and Loprasert does not teach a method using a nucleic acid of the invention. Loprasert is not a single prior source that contains each and every limitation of the claimed invention. Loprasert cannot be used as evidence that Trakulnaleamsai is a single prior source that contains each and every limitation of the claimed invention.

Applicants respectfully aver that, after entry of the instant amendment, Trakulnaleamsai, as evidenced by Loprasert, is not a single prior source that contains each and every limitation of the claimed invention. Accordingly, the rejection of the claims under 35 U.S.C. § 102(b) as allegedly anticipated by Trakulnaleamsai, as evidenced by Loprasert, can be withdrawn.

Issues under 35 U.S.C. § 103

*Trakulnaleamsai in view of the Short '250 patent*

Claims 42 to 55 are rejected under 35 USC § 103(a) as allegedly unpatentable over Trakulnaleamsai in view of the Short '250 patent.

The Patent Office states that Trakulnaleamsai is defective in teaching the claimed methods of the instant invention in that it does not use the methods of mutagenesis specifically recited in claims 44 to 53 to produce a mutant catalase.

However, Applicants respectfully aver that Trakulnaleamsai is further defective in that, inter alia, it does not teach a nucleic acid of the invention or a method using a nucleic acid of the invention, e.g., a sequence as set forth in SEQ ID NO:7 or a sequence having at least about 50% sequence identity to a sequence as set forth in SEQ ID NO:7, or, (after entry of the instant amendment) a sequence as set forth in SEQ ID NO:5 or a sequence having at least about 65% sequence identity to a sequence as set forth in SEQ ID NO:5.

The Patent Office notes that the Short '250 patent teaches a number of techniques for directed mutagenesis. However, the Short '250 patent does not cure the defects in Trakulnaleamsai. The Short '250 patent does not teach or suggest a nucleic acid of the invention

or a method using a nucleic acid or the invention, e.g., a sequence as set forth in SEQ ID NO:7 or a sequence having at least about 50% sequence identity to a sequence as set forth in SEQ ID NO:7, or, (after entry of the instant amendment) a sequence as set forth in SEQ ID NO:5 or a sequence having at least about 65% sequence identity to a sequence as set forth in SEQ ID NO:5. Accordingly, Trakulnaleamsai in view of the Short '250 patent does not teach or suggest the claimed invention.

*Trakulnaleamsai in view of the Short '258 patent*

Claims 42, 43, 54 and 55 are rejected under 35 USC §103(a) as allegedly unpatentable over Trakulnaleamsai in view of the Short '258 patent.

The Patent Office states that Trakulnaleamsai is defective in teaching the claimed methods of the instant invention in that it does not use the methods of mutagenesis specifically recited in claims 44 to 53 to produce a mutant catalase.

However, Applicants respectfully aver that Trakulnaleamsai is further defective in that, inter alia, it does not teach a nucleic acid of the invention or a method using a nucleic acid or the invention, e.g., a sequence as set forth in SEQ ID NO:7 or a sequence having at least about 50% sequence identity to a sequence as set forth in SEQ ID NO:7, or, (after entry of the instant amendment) a sequence as set forth in SEQ ID NO:5 or a sequence having at least about 65% sequence identity to a sequence as set forth in SEQ ID NO:5.

The Patent Office notes that the Short '258 patent teaches a number of techniques for non-stochastic methods of directed mutagenesis for the development of modified enzymes.

However, the Short '258 patent does not cure the defects in Trakulnaleamsai. The Short '258 patent does not teach or suggest a nucleic acid of the invention or a method using a nucleic acid or the invention, e.g., a sequence as set forth in SEQ ID NO:7 or a sequence having at least about 50% sequence identity to a sequence as set forth in SEQ ID NO:7, or, (after entry of the instant amendment) a sequence as set forth in SEQ ID NO:5 or a sequence having at least about 65% sequence identity to a sequence as set forth in SEQ ID NO:5. Accordingly, Trakulnaleamsai in view of the Short '258 patent does not teach or suggest the claimed invention.

CONCLUSION

Applicants request that the Examiner reconsider the application and claims in light of the foregoing reasons and amendments and respectfully submit that the claims are in condition for allowance.

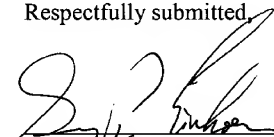
If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues and to work with the Examiner toward placing the application in condition for allowance.

If any necessary additional such fees are due, the Commissioner is hereby authorized to charge any such fees to Deposit Account No. 06-1050. Overcharges can be credited to the same account.

Respectfully submitted,

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